

Pulpdent Sealant / Paste Orthodontic Bracket Adhesive System

EXHIBIT 2

K020115

FEB 28 2002

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

RESPONSE TO SMDA OF 1990

Kenneth J. Berk
80 Oakland Street
PO Box 780
Watertown, MA 02472 USA

Telephone: 617-926-6666
Fax: 617-926-6262

DEVICE

TRADE NAME: *PULPDENT Sealant/ Paste Orthodontic Bracket Adhesive System***CLASSIFICATION NAME:** Adhesive, Bracket and Tooth Conditioner, Resin**FDA Product Code:** 76 DYH, 21 CFR Part 872.3750

PREDICATE DEVICES:

GAC *AccuBond* Sealant/Paste Bonding System
GAC *ExactaBond* Sealant/Paste Bonding System
Reliance *Excel* Bonding Adhesive
Reliance *Phase 11* Sealant/Paste System
3M *Concise* Orthodontic Bond System

DESCRIPTION AND INTENDED USE:

PULPDENT Sealant/Paste Orthodontic Bracket Adhesive System is a self-cure, two-paste dental adhesive used with a self-cure, two-part sealant to adhere orthodontic brackets to tooth surfaces.

COMPARISON WITH PREDICATE PRODUCTS:

PULPDENT Sealant/Paste Orthodontic Bracket Adhesive System is substantially equivalent in composition and intended use to the predicate products listed above. Please see Exhibit 4 for the entire comparison.

SAFETY AND EFFECTIVENESS:

According to the NIH Technology Assessment Conference on *Effects and Side-Effects of Dental Restorative Materials*: "General usage of these materials over about 20 years indicates a high benefit-to-risk ratio...both composites and glass ionomers are relatively trouble-free. There is no evidence of short-term or long-term risk...There is no suspicion of any problems after virtually billions of procedures in the United States. In addition, the predicate products listed above have been given 510 (k) premarket approval as Class II Dental Devices under CFR 872.3750.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2002

Mr. Kenneth J. Berk
Director
Puldent Corporation
80 Oakland Street
Watertown, Massachusetts 02472

Re: K020115

Trade/Device Name: Puldent Sealant/Paste Orthodontic Bracket Adhesive
Regulation Number: 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Codes: DYH
Dated: January 04, 2002
Received: January 11, 2002

Dear Mr. Berk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

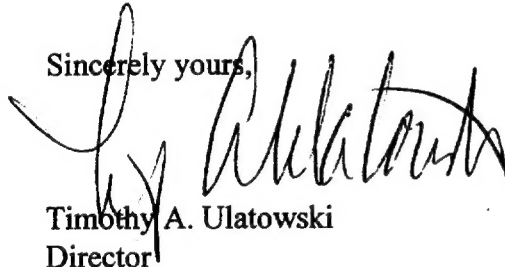
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski
Director

Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (k) Number
(if known)

K020115

Device Name: **PULPDENT Sealant / Paste Orthodontic Bracket Adhesive System**

Indications for Use:

PULPDENT Sealant/Paste Orthodontic Bracket Adhesive System is a self-cure, two-paste dental adhesive used with a self-cure, two-part sealant to adhere orthodontic brackets to tooth surfaces.

Please do not write below this line. Continue on another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

or

Over-The-Counter Use

Susan R. R...

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020115